5. 510(k) Summary of Safety and Effectiveness

Reaonix Security, LLC
2434 Malden Park Dr.
Buford, GA 30519

DEC 10 2009

Date Summary Prepared:
June 5, 2009

Contact Person:
Gerald Jackson
Reaonix Security, LLC
Telephone: 678-985-3434
Fax: 678-985-3434

Device Name: Presidio PACS
Trade Name(s): Presidio PACS
Classification Name: Picture Archiving and Communications System
Classification Regulation: Class II - 892.2050
Panel Code Device: Radiology
Product Code: LLZ

Predicate Device Information:
Device Name: IMAGESVR PACS
Manufacturer: JAGUAR TECHNOLOGY LIMITED
Reference: K082808

Device Name: DATACOM DC PACS
Manufacturer: DATACOM TECHNOLOGY CORP.
Reference: K083182

Device Description:
The Presidio PACS include the following major components: Workstation, Enterprise and RIS.

The Presidio PACS workstation is used to view, edit, manipulate, annotate, analyze, store and distribute images and data that are stored and managed in the Presidio PACS Enterprise for diagnosis. This software-based product provides capabilities for the acceptance, transmission, printing, display, storage, editing and digital processing of medical images and associated data.

All acquired image data is preserved in the format in which it is received. Changes may be made to the presentation of the images. These changes are saved as display definitions only and do not alter the acquired image pixel data. Any and all display definitions applied to an image can always be reversed to the acquired state.

The Presidio PACS workstation may also be used in a remote location, away from the healthcare facility, as long as the workstation has the ability to connect, via network, to the primary healthcare facility where the Presidio PACS Enterprise is located.

The Presidio PACS Workstation extends its diagnostic and productivity capabilities into the mammography reading environment and may also be used for the primary interpretation of digital mammography images with a FDA approve 5MP monitor.

The Presidio PACS Workstation has a modular software architecture which allows adding addition feature or enhancements in the form of plug-ins without any modification to the existing software code base.

Presidio PACS Enterprise software delivers a complete, scalable storage solution for diagnostic images. Images can be stored in uncompressed, lossless or lossy. The system also has the ability to send data to DICOM ready devices via the DICOM standard protocol. It is a DICOM compliant solution for image storage, retrieval and transmission. The Enterprise Archive provides redundancy in long-term storage in several ways, including Redundant Archives, Media Copy, and Application Service Provider (ASP) Archive.

Presidio RIS provides a hospital or clinic with automated tools to electronically schedule and manages patient exam information. The Presidio RIS utilizes a Workstation client that provides referring physicians the added flexibility to instantly view and schedule their own patients' radiographic services.

The Presidio PACS software application is a software only solution and will use 'off the shelf' PC and server hardware technology that meets defined minimum specifications.

Intended Use:
The Presidio PACS software is intended for the manipulation, management, and display of medical images. It can manage and display images from different modalities and interfaces and can distribute those images to various workstation, image storage and printing devices using DICOM or similar standards. Typical users of this system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.

To support the diagnostic interpretation of mammography studies, Presidio PACS will display the full fidelity DICOM image in a non-compressed format. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation.

It is the user's responsibility to ensure quality, ambient light conditions and image compression ratios are consistent with the clinical application.

Comparison to Predicate Device(s):

Product Name	Presidio PACS	ImageSVR PACS	DATACOM DC-PACS
510(k) Number		K082808	K083182
Communications	TCP/IP	TCP/IP	TCP/IP
Image Archive	YES	YES	YES
Image Processing	Yes	YES	YES
Image Edit	Yes	YES	YES
Edit Patient Demographics	YES	YES	YES
Add and remove images	YES	YES	YES
Combine studies	YES	YES	YES
Edit Patient Orientation Information	YES	YES	YES
Set and Edit Routing Informatiion	YES	YES	YES
JPEG Lossy/Lossless Compression	YES	YES	YES
JPEG 2000 Lossy/Lossless Compression	YES	YES	NO
Image Processing (Image segmentation, image smoothing)	YES	YES	YES
Image Processing (Window Level, Pan, Zoom,Variable Smooth Filter, Cine Display)	YES	YES	YES
DICOM Print	YES	YES	YES

SUBSTANTIAL EQUIVALENCE CONCLUSIONS:
A claim of substantial equivalence is made to ImageSVR (K082808) and DATACOM DC-PACS (K083182). All of them have the same working principle and technologies. The differences are due to the feature design aspects, not relating to the safety or effectiveness aspects. Besides, the submission contains the results of software validation that the risks analysis and the potential hazards have been classified Minor.

Thus they are substantially equivalent.

Technological Characteristics:
The device does not contact the patient, nor does it control any life sustaining devices. The software does not provide any diagnostic assistance to the physician. Any diagnostic determination or treatment is solely determined by a physician and not the software. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed and printed.

SAFETY INFORMATION:
The Presidio PACS has no patient contact and is utilized only by trained professionals. Trained professionals allow sufficient review to give identification and intervention in the event of a malfunction. Patient data is limited to authorized individuals. The Presidio PACS utilize "off-the-shelf" servers and Personal computers. It complies with applicable electrical safety standards for standard hardware and peripherals.

TESTING AND CONCLUSIONS:
Software validation has established the device's ability to meet its intended use and established specifications. The information provided in this traditional premarket notification submission has shown that the Presidio PACS is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 10 2009

Mr. Gerald Jackson
CEO
Reaonix Security, LLC
2434 Malden Park Dr.
BUFORD GA 30519

Re: K092125
Trade/Device Name: Presidio PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 20, 2009
Received: November 23, 2009

Dear Mr. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indication for Use Statement

Indications for Use
510(k) Number (if known): ~~TBD~~ K092125
Device Name: Presidio PACS

Indications for Use:
The Presidio PACS software is intended for the manipulation, management, and display of medical images. It can manage and display images from different modalities and interfaces and can distribute those images to various workstation, image storage and printing devices using DICOM or similar standards. Typical users of this system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.

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Prescription Use XXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092125